## Remarks

The Final Office Action mailed May 7, 2010 has been carefully considered. Reconsideration and allowance of the subject application, as amended, are respectfully requested.

Claims 40-63 and 65-75 remain pending in the application. Claims 74 and 75 were withdrawn due to an Election/Restriction requirement. Claim 51 has been cancelled and the matter included in amended claim 40.

Independent claim 40 has been amended to recite "An implantable device to be used in a human and/or animal body for at least partially occluding defect openings, hollow spaces or organ tracts or for creating a defined connecting opening between two walls, organs and hollow spaces in said body, comprising: a support structure having a shape having a first length-to-width ratio along an axis in a first operating state and having a secondary shape having a second length-to-width ratio along said axis in a second operating state wherein said first length-to-width ratio is greater than said second length-to-width ratio, the support structure having two ends, a proximal portion, an intermediate portion, a distal portion and a surface, the support structure comprising a single intertwined, inter-coiled wire-like element having two ends having a tissue and/or scrim and/or net structure, wherein the proximal portion and/or distal portion in the secondary shape is substantially flat in a disk shape or ring shape or at least bent round in an edge area of said proximal portion or bent back toward the other of the distal or proximate portion or bent outward from said intermediate portion connecting the distal and proximal portions, so that a delimited inner space is formed, said inner space including an opening, wherein said two ends of said wire-like element are both arranged at one end of said support structure or are integrated into the surface of the support structure." Support may be found at paragraphs [**0082-0084**] regarding the shapes and an inner space/through opening and in dependent claim 51 for "said two ends of said wire-like element are both arranged at one end of said support structure or are integrated into the surface of the support structure." No new matter has been entered.

Dependent claim 46 has been rejected under 35 U.S.C. § 112, second paragraph, for not providing proper antecedent basis for "the area of application". Claim 46 has been amended to recite "an" area of application of the device. No new matter has been entered.

Dependent claim 48 has been rejected under 35 U.S.C. § 112, second paragraph, for not providing proper antecedent basis for "the material concentration" and "the material thickness". Claim 48 has been amended to recite "The implantable device as claimed in claim 47, wherein said wire-like element of the support structure has a thickness and a concentration of material and said thickness and concentration of material is different across the implantable device from distal to proximate portion." Support may be found in paragraph [**0022**]. No new matter has been entered.

Dependent claim 49 has been rejected under 35 U.S.C. § 112, second paragraph, for being unclear regarding "a wire-like element" of claim 40. Claim 49 has been amended to recite "The implantable device as claimed in claim 48, wherein said support structure includes partial areas which are formed from a single wire-like element having different diameters." Support may be found in paragraph [**0028**]. No new matter has been entered.

Dependent claim 50 has been rejected under 35 U.S.C. § 112, second paragraph, for not clearly indicating that the amount and the concentration of wire-like element refer to the wire-like element of claim 40. Claim 50 has been amended to recite "The implantable device as claimed in claim 48, wherein said concentration of material of said wire-like element in the edge area of the implantable device provides for partial stiffening." Support may be found at paragraph [**0022**]. No new matter has been entered.

Claims 52, 53, 54, 57, 58, 61, 65, 67, 68, 70, 71 and 73 have been amended to remove indefinite language or add clarifying language or punctuation. No new matter has been entered.

Dependent claim 55 has been rejected under 35 U.S.C. § 112, second paragraph, for not clearly indicating how individual parts of the support structure may correspond. Claim 55 has been amended to recite "The implantable device as claimed in claim 54, wherein the individual parts of the two-part or multi-part unit of the support structure are designed uniformly, corresponding to one another." Support may be found in paragraph [**0027**]. No new matter has been entered.

Dependent claim 62 has been rejected under 35 U.S.C. § 112, second paragraph, for not providing proper antecedent basis for "said edge area". Claim 40 has been amended to recite

that the proximal portion structure has an edge area. Support may be found in paragraph [**0084**]. No new matter has been entered.

Turning to the rejections, claims 40-59 and 63, 65 and 66 have been rejected under 35 U.S.C. § 103(a) as being anticipated by Amplatz et al. (US 5,944,738) in view of either Andersen et al. (US 5,876,445) or Shaw et al. (US 6,171,329). To the extent that the Examiner considers the art of record applicable to the amended claims, it is noted as follows.

Amplatz et al. appears to be directed at a collapsible medical device comprising a tubular metal *fabric* of woven metal *strands*, the device collapsible for delivery into a patient's body. The reference appears to be directed at a wire braid (woven strands). There is no reference to a support structure comprising a single wire element having two ends that has been coiled or intertwined (with itself). See amended claim 40. Also see **FIG. 6**, of the present application, reference numerals **11** and **12** which represent the respective ends of the wire-like element device **1** having proximal, distal and intermediate portions.

The Office Action admits at page 5 that Amplatz et al do not disclose that the support structure is formed from a single wire-like element and turns to Andersen et al. The construction of Amplatz et al. requires clamps (**30, 32**) at the ends of the wire braids to avoid unraveling. In case where the construction of Andersen et al. is combined with the construction of Amplatz et al., the ends of the stent disclosed by Andersen et al. have to be clamped since no other construction is disclosed at Amplatz et al.

Further, the present invention provides a self-centering effect by adapting to the middle section of a shape of an opening, which is again not possible with the device of Amplatz et al. since the intermediate portion of the Amplatz et al. device is not able to adapt to a defect opening when inserted into such and the device is also too small for being able to adapt to such an opening. When being inserted into an opening the device according to the present invention allows the intermediate portion to adjust its diameter to fit into the opening and bias against its walls because of the at least one disk being a one layer disk. This one layer disk provides the possibility to "roll" or "flow" in its plane in the direction of the intermediate portion such that there is enough material for increasing or reducing its diameter to adapt to the defect opening diameter.

Andersen et al. appears to be directed at a medical stent formed by **knitting** a nitinol wire into a pattern. While in one embodiment, **FIG 4a**, the stent is described as being knitted from a

single filament, note that the stent is knitted and as such is capable of unraveling, and accordingly, the last three loops of the stent are coated in urethane (Column 8 lines 38-40).

Amended claim 40 recites that the support structure "comprises a single intertwined, intercoiled wire-like element having two ends" (emphasis added) and does not involve **knitting** a stent of constant diameter and geometry (Column 12, lines 58-63). Therefore, any coating of loops to prevent unraveling is not necessary with the device according to the present invention.

Further, there would not seem to be motivation to combine Amplatz et al. and Andersen et al., as suggested by the Examiner, since Amplatz et al. is directed at a device for closing abnormal openings in humans (see Abstract), and Andersen et al. is directed at a device for maintaining an opening in an open condition, that is, the knitted wire stent expands outward against the body lumen wall (esophagus) and holds the esophagus open (Column 2 lines 1-4 of Andersen et al.).

Shaw et al. appears to be directed at a self-expanding device for sealing a defect in a wall, such as a septal defect. The device has a helical shaped wire periphery formed from an elastic wire and at least one eyelet. Further, Shaw et al. requires a membrane element be attached to the frame in order to close the opening in the wire periphery. The present invention does not form a helix and does not include eyelets. In addition, in the present invention the single coiled wire is sufficient to be shaped to occlude defect openings such that no additional membrane element is necessary to build an occluding device. The device of Shaw et al. can not be used as an occluding device without the membrane element. Thus, Shaw et al. does not disclose an occluding device made of a single wire.

Since the device of Shaw et al. differs from the device of Amplatz et al. there is no hint how to combine these ideas of making occluding devices. Especially, as just mentioned above, Amplatz et al. demands clamps at the ends of the device to collect together the number of wire strands.

Claims 60-62 have been rejected under 35 U.S.C. § 103(a) as being anticipated by Amplatz et al. (US 5,944,738) in view of either Andersen et al. (US 5,876,445) or Shaw et al. (US 6,171,329) and further in view of Gainor et al. (US 2002/0169475). The deficiencies of Amplatz et al. Andersen et al. and Shaw are discussed above.

Gainor et al. appears to be directed at a septal defect closure device having 2 wire frames, each with a fabric membrane, wherein in the present invention the single coiled wire is sufficient

to be shaped to occlude defect openings. Without providing the two membranes in addition to the wire frames no occluding effect is possible with the device according to Gainor et al.

Further, none of the prior art documents of Amplatz et al., Andersen et al., Shaw et al., and Gainor et al. provides the possibility of self-centering by adapting the diameter of the intermediate portion to the diameter of the defect opening. Because of the self-centering effect the device according to the present invention positions itself in the defect opening in the correct orientation.

Claims 67-73 have been rejected under 35 U.S.C. § 103(a) as being anticipated by Amplatz et al. (US 5,944,738) in view of Shaw et al. (US 6,171,329). Shaw et al. does teach a positioning system but does not teach or suggest a support structure that "comprises a single intertwined, intercoiled wire-like element having two ends". Further, the positioning system differs from the positioning system according to the present invention. No retaining wire and guide wire are moved relative to an advancing element of Amplatz et al. or Shaw et al. Further, neither Amplatz et al. nor Shaw et al. disclose any auxiliary structure for aiding the deployment of the implantable device.

Having dealt with all the objections raised by the Examiner, it is respectfully submitted that the present application, as amended, is in condition for allowance. Thus, early allowance is earnestly solicited.

If the Examiner desires personal contact for further disposition of this case, the Examiner is invited to call the undersigned Attorney at 603.668.6560.

In the event there are any fees due, please charge them to our Deposit Account No. 50-2121.

Respectfully submitted,

By: /Steven J. Grossman/
Steven J. Grossman, Ph.D.
Reg. No. 35,001